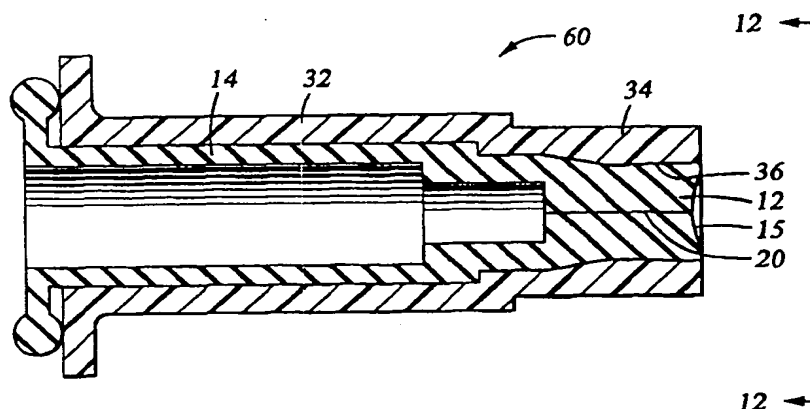




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 5/00		A1	(11) International Publication Number: WO 98/23313
			(43) International Publication Date: 4 June 1998 (04.06.98)
(21) International Application Number: PCT/US97/21521		(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 21 November 1997 (21.11.97)		Published <i>With international search report.</i>	
(30) Priority Data:			
08/757,156	27 November 1996 (27.11.96) US		
08/857,086	15 May 1997 (15.05.97) US		
(71) Applicant: ELCAM PLASTICS [IL/IL]; Kibbutz Bar-Am, M.P. Merom, 13860 Hagalil (IL).			
(71)(72) Applicant and Inventor: THOMPSON, John [US/US]; 2924 Calle Frontera, San Clemente, CA 92673 (US).			
(72) Inventors: ZINGER, Freddy; 29 Kazan Street, 43611 Raanana (IL). ZIV, David; Kibbutz Bar-Am, M.P. Merom, 13860 Hagalil (IL).			
(74) Agent: SPINKS, Gerald, W.; P.O. Box 10158, College Station, TX 77842 (US).			

(54) Title: NEEDLELESS VALVE



(57) Abstract

This invention is a needleless valve connector which employs a pre-slit elastomeric septum (12) capable of axial movement proximally and distally within a housing. Connection of a blunt connector to the housing pushes the septum in the distal direction. A spring member (14) biases the septum toward the proximal direction. The slot (20) through the septum is held in the closed position, when the septum is in the proximal position by an interference fit between the inside surface of the housing, and the peripheral surface of the septum, with the interference fit causing an inward radial compression of the septum, orthogonal to the slit axis. The outer, or proximal end surface of the septum can be shaped with a concave contour which causes the slit to completely close when the septum is in the proximal position. When a blunt connector is connected to the housing the septum is pushed to a distal position, where the radial stress on the septum is modified, allowing the septum to expand or be expanded, thereby opening the slit. The axial locations of the housing structures which vary the radial loads to open and close the slit, are selected to insure that the septum is sealed before the septum fully reaches the proximal position, thereby maintaining a seal between the blunt connector and the septum until after the slit is sealed. The structure which opens the slit, or allows the slit to open, is positioned to open the slit only after sufficient force is applied to the septum by the blunt connector, to insure that a seal exists between the blunt connector and the septum before opening of the slit.

THIS PAGE BLANK (USPTO)

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

TITLE OF THE INVENTION

Needleless Valve

BACKGROUND OF THE INVENTION

5 It is a well known practice to administer medications and other types of solutions to a patient with an intravascular administration set, consisting of a needle inserted into a blood vessel of the patient, flexible tubing connected to the needle, and various fittings for connecting fluid components to the flexible tubing. The fluid components can be a bottle of parenteral fluid, a bottle of a supplementary fluid, or a syringe of medication.

10 Typically, one solution will be connected to flow continuously into the patient, while another solution will be added to the first solution at a branch connector located in the flexible tubing. Such connectors are often called "Y-sites". A Y-site is usually a sealed entry point having an elastomeric plug or septum. Medication can be introduced into the Y-site by injection through the elastomeric septum with a second needle, or by connecting

15 a blunt connector to the Y-site, with flow through or past the septum being achieved by various means. Many connector devices in addition to the Y-site use the elastomeric septum for connection of fluid flow paths.

A major drawback of using a needle to penetrate the septum is that the use of sharp needles in any device frequently results in the occurrence of "needle stick" accidents, in which health care personnel are accidentally wounded by the needle. The

20 needle stick accident can occur during insertion of the needle into the Y-site, or after use of the needle and before disposal. Needle stick accidents often spread infectious diseases, such as the HIV virus. This risk arises any time a sharp needle is used to connect two fluid flow components, not being restricted to the use of a Y-site in an I. V. set. Various

25 devices have therefore been developed, which do not use a sharp needle, using instead a blunt device to connect to the Y-site or other connector. Most common among the "needle-less" connectors is the use of a luer connector, with an elastomeric septum in the female component, such as the Y-site, and a blunt male connector for connecting thereto. When the male luer connector is connected to the female luer connector, the septum is

30 either pierced by a concealed piercing element, or the septum is otherwise penetrated or bypassed.

In a needle-less connector, there is typically a certain amount of dead space within the connector in which the septum is mounted, such as the Y-site. This allows for shifting or deformation of the septum, to achieve fluid flow. Unfortunately, dead space is undesirable, because it allows for the injection of air or contaminants into the patient along with the medication, accumulation of medication in a stagnant space, or coagulation of accumulated blood.

Further, needle-less connectors often allow the generation of a vacuum when the luer connector is disassembled. The vacuum results when a movable septum moves outwardly within the Y-site or other connector, upon disconnection, creating a lower than ambient pressure in the connector. If the septum is not sealed sufficiently to withstand the pressure differential before the connectors lose contact, flow from the ambient into the connector can occur. This vacuum can draw contaminants from the environment into the Y-site.

Another problem frequently associated with pre-slit needle-less connector devices is the failure of the opening in the septum to completely close at its outermost end, sometimes leaving a partially open slit in which contaminants can accumulate. Prior to use of the connector, it is common practice to wipe clean the exterior surface of the septum with alcohol, to remove contamination. However, if the septum has a slit which fails to completely close, the outer extremity of the slit can harbor contaminants which can not be effectively cleaned by wiping.

Finally, many known needle-less connectors suffer from the failure to seal against a required pressure differential. This can result from the absence of any structure in the housing to positively close the septum upon withdrawal of the blunt connector.

It is desirable, therefore, to have a needle-less connector which can be incorporated into a Y-site or any other type of fluid flow connector, which will limit the amount of dead space, counteract the formation of a vacuum, completely seal upon withdrawal of the associated connector, and effectively seal against significant pressure differentials.

BRIEF SUMMARY OF THE INVENTION

The present invention is a needle-less valve connector which employs a pre-slit elastomeric septum within a rigid housing such as a Y-site. The septum is capable of

axial movement proximally and distally within the Y-site. Connection of a blunt connector, such as a male luer, to the female fitting on the Y-site pushes the septum in the distal direction. A spring or other biasing member biases the septum toward the proximal direction. The slit through the septum is held in the closed position, when the septum is
5 in the proximal position, by an interference fit between the inside surface of the housing and the peripheral surface of the septum, with the interference fit causing an inward radial compression of the septum, orthogonal to the slit axis. The interference fit must be sufficient to seal the slit against a pressure differential of at least 30 psi. The interference fit can be caused by using a septum having an elliptical cross section and a housing
10 having a circular cross section, with at least one axis of the septum being larger than the inside diameter of the housing, that being the axis of the septum cross section which is orthogonal to the slit axis. Conversely, the septum could have a circular cross section, and the housing could be irregular or elliptical. In this type of device, the minor axis of the housing cross section would be positioned orthogonal to the slit axis in the septum.
15 The outer, or proximal, end surface of the septum can be shaped with a concave contour which places the outer end of the slit at the axial location at which sufficient inward radial stress exists to completely close the slit when the septum is in the proximal position. This prevents the existence of a crevice at the outer extremity of the slit when the valve is closed.

20 When the blunt connector is connected to the valve, the septum is pushed to a distal position, where another contour in the housing either applies a radial force to the septum to open the slit, or allows the septum to expand, thereby opening the slit. This opening of the slit can be achieved in three ways. First, another interference fit between the inside surface of the housing and the peripheral surface of the septum can be used to
25 apply inward radial stress to the septum, parallel to the slit axis, causing the slit to open as the septum moves in the distal direction. Here again, the septum could be irregularly shaped and the housing circular, or the septum could be circular and the housing irregular. Second, a hollow cannula in the distal end of the housing can be aligned with the slit to forcibly enter the distal end of the slit and apply outward radial stress to the septum,
30 orthogonal to the slit axis, causing the slit to open as the septum moves in the distal direction. These two methods of applying radial stress to open the slit can be used separately, or in combination. Third, a cavity in the housing, which is at least as large in

cross section as the septum, allows the septum to expand to a condition in which the slit is no longer held closed.

The axial locations of the housing structures which vary the radial loads to open and close the slit are selected to insure that the septum is sealed at all appropriate times.

5 The structure which closes the slit is positioned to close and seal the slit before the septum fully reaches the proximal position, thereby maintaining a seal between the blunt connector and the septum until after the slit is sealed, preventing vacuum contamination. The structure which opens the slit, or allows the slit to open, is positioned so that the slit will open only after sufficient force is applied to the septum by the blunt connector, to
10 insure that a seal exists between the blunt connector and the septum before opening of the slit.

The novel features of this invention, as well as the invention itself, will be best understood from the attached drawings, taken along with the following description, in which similar reference characters refer to similar parts, and in which:

15

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a first embodiment of an elliptical septum and a spring member according to the present invention, in the unconstrained condition;

Figure 2 is a longitudinal section, orthogonal to the slit axis, of the septum shown
20 in Figure 1;

Figure 3 is a longitudinal section, parallel to the slit axis, of the septum shown in Figure 1;

Figure 4 is a perspective view of a second embodiment of an elliptical septum and a spring member according to the present invention, with the septum having a higher
25 aspect ratio between its major and minor axes;

Figure 5 is a longitudinal section, orthogonal to the slit axis, of the septum shown in Figure 4;

Figure 6 is a longitudinal section, parallel to the slit axis, of the septum shown in Figure 4;

30 Figure 7 is a partial section of a first embodiment of a female valve connector housing according to the present invention, with wings projecting inwardly to apply inward radial stress to the septum in the distal position;

Figure 8 is a longitudinal section, orthogonal to the plane of the wings, of the housing shown in Figure 7;

Figure 9 is a longitudinal section, parallel to the plane of the wings, of the housing shown in Figure 7;

5 Figure 10 is a partial section of the housing shown in Figure 7, showing the introduction of a blunt connector;

Figure 11 is a longitudinal section, orthogonal to the plane of the wings and orthogonal to the slit axis, of the septum shown in Figure 1 installed in the housing shown in Figure 7, with the septum in the proximal position;

10 Figure 12 is an end view of the valve assembly shown in Figure 11;

Figure 13 is a longitudinal section, parallel to the plane of the wings and parallel to the slit axis, of the septum shown in Figure 1 installed in the housing shown in Figure 7, with the septum in the distal position;

Figure 14 is an end view of the valve assembly shown in Figure 13;

15 Figure 15 is a perspective view of a second embodiment of a female valve connector housing according to the present invention;

Figure 16 is a longitudinal section of the housing shown in Figure 15, with a blunt cannula projecting in the proximal direction;

20 Figure 17 is a perspective view of the housing shown in Figure 15, showing the introduction of a blunt connector;

Figure 18 is a longitudinal section of the septum shown in Figure 4 installed in the housing shown in Figure 15, with the septum in the proximal position;

Figure 19 is an end view of the valve assembly shown in Figure 18;

25 Figure 20 is a longitudinal section of the septum shown in Figure 4 installed in the housing shown in Figure 15, with the septum in the distal position;

Figure 21 is an end view of the valve assembly shown in Figure 20;

30 Figure 22 is a perspective view of a third embodiment of an elliptical septum and a spring member according to the present invention, with the septum having a higher aspect ratio between its major and minor axes, and with the slit axis being aligned with the major axis of the septum;

Figure 23 is a longitudinal section, parallel to the slit axis, of the septum shown in Figure 22;

Figure 24 is a longitudinal section, orthogonal to the slit axis, of the septum shown in Figure 22;

Figure 25 is a partial section of a third embodiment of a female valve connector housing according to the present invention, with an elliptical distal interior contour;

5 Figure 26 is a longitudinal section, along the major axis of the elliptical interior contour, of the housing shown in Figure 25;

Figure 27 is a longitudinal section, along the minor axis of the elliptical interior contour, of the housing shown in Figure 25;

10 Figure 28 is a longitudinal section, orthogonal to the slit axis, of the septum shown in Figure 22 installed in the housing shown in Figure 25, with the septum in the proximal position;

Figure 29 is an end view of the valve assembly shown in Figure 28;

15 Figure 30 is a longitudinal section, orthogonal to the slit axis, of the septum shown in Figure 22 installed in the housing shown in Figure 25, with the septum in the distal position; and

Figure 31 is a sectional view of the valve assembly shown in Figure 30.

DETAILED DESCRIPTION OF THE INVENTION

20 Figure 1 shows a hollow, combination elastomeric valve element 10 comprising a septum 12 and a spring element 14. In this view, the valve element 10 is in the unconstrained condition. The spring element can be a resilient elastomeric cylinder as shown, or it can be a spring, such as a coiled spring, in substantially the same location. If a coiled spring is used, it can be separate from the valve element 10 or integrated into the valve element 10. The septum 12 shown has an elliptical cross section, with a major
25 transverse dimension, or major axis 16, and a minor transverse dimension, or minor axis 18. The septum 12 has a peripheral surface 13 and a proximal end surface 15. The septum 12 also could be another non-cylindrical shape without departing from the spirit of the invention. Further, depending upon the shape of other elements of the valve, the septum 12 could even have a cylindrical shape, as will be discussed later. A slit 20 is formed
30 longitudinally through the septum 12. The cross section of the slit 20 can be a flat line, or slightly oval as shown, with a slit plane 22. The slit plane 22 is orthogonal to the major

transverse dimension 16 of the septum 12. The end surface 15 has a concave surface 17 which ensures that the outer end of the slit 20 remains closed.

Figure 2 shows a longitudinal cross section of the valve element 10, with the section being taken orthogonal to the slit plane 22. The longitudinal axis 24 of the valve element 10 can lie in the slit plane 22 as shown, or it can be offset therefrom. The valve element 10 also can have a sealing bead 26 near its distal end, to facilitate sealing the valve element to a housing, such as a Y-site. The configuration and location of the sealing member 26 can vary, to match the housing in which the valve element 10 is used. There can also be a tapered neck 28 in the valve element 10, to allow relative axial movement between the septum 12 and the remainder of the valve element 10. The neck 28 is also an alternative location for a spring element. The neck 28 can be provided with slots 29 to provide clearance for housing structure, as will be explained below. Figure 3 shows another longitudinal cross section of the valve element 10, with the section being taken at, or in a plane parallel to, the slit plane 22. It can be seen from Figures 1 through 3 that the aspect ratio between the major transverse dimension 16 and the minor transverse dimension 18 of the septum 12 is not very much greater than unity, so the septum 12 is not far from being cylindrical in this embodiment.

Figure 4 shows a second embodiment of the elastomeric valve element 10', with a septum 12' and a spring element 14. Here again, the slit plane 22 is orthogonal to the major transverse dimension 16 of the septum 12'. Figure 5 shows a longitudinal cross section of the valve element 10', with the section being taken orthogonal to the slit plane 22. The slit plane 22 can contain the longitudinal axis 24 of the valve element 10, or it can be offset therefrom. Figure 6 shows another longitudinal cross section of the valve element 10', with the section being taken at, or parallel to, the slit plane 22. In this embodiment, the aspect ratio between the major transverse dimension 16 and the minor transverse dimension 18 is much higher than in the first embodiment, making the septum 12' further from a cylindrical shape. A higher aspect ratio could be selected to apply higher radial stress to the septum 12, 12', or to provide more room for expansion of the minor transverse dimension 18 of the septum 12, 12'.

Figure 7 shows a first embodiment of a rigid tubular connector housing 30 with which the valve element 10 can be used. The connector housing 30 includes generally a hollow, substantially cylindrical barrel 32 and a substantially cylindrical tubular valve

housing 34 formed on a proximal end of the barrel 32. The connector housing 30 can also be fitted with a flange 50 for sealing against the sealing bead 26 of the valve element 10, if appropriate for the type of connector. The configurations shown for the distal ends of the connector housing 30 and the valve element 10, such as the flange 50 and the sealing element 26, are for illustration purposes only, with the actual configuration being adapted to the actual connector being designed. The tubular valve housing 34 has an inside surface 36 which interacts with the peripheral surface 13 of the septum 12, to place inward radial stress upon the septum 12 as desired to open or close the slit 20.

The interaction between the inside surface 36 of the valve housing 34 and the peripheral surface 13 of the septum 12 has two modes, one occurring when the septum 12 is positioned near the proximal end 38 of the valve housing 34 and the other occurring when the septum 12 is positioned near the distal end 40 of the valve housing 34. In this embodiment, the proximal portion of the inside surface 36 of the valve housing 34 has a circular cross section, as can be seen in Figures 8 and 9. The distal portion of the inside surface 36 of the valve housing 34 has two diametrically opposed inwardly sloping wings 42, 44. The distance between the wings 42, 44 is less than the internal diameter of the proximal portion of the valve housing 34, and less than the minor transverse dimension 18 of the septum 12. Except for the wings 42, 44, the internal surface 36 of the distal portion of the valve housing 34 has a conical surface 46 tapering outwardly to a larger diameter 48 at the distal end 40. As mentioned above, instead of making the septum 12 with an elliptical cross section and the valve housing interior surface 36 with a circular cross section, the septum 12 could be circular and the valve housing 34 could be elliptical. Any such combination of corresponding shapes of the septum 12 and the valve housing 34 which results in an inward radial stress being placed on the septum 12 will comport with the spirit of the invention.

Figures 10 through 14 illustrate the interaction of the valve housing 34 and the septum 12, when assembled as a valve assembly 60. The particular valve housing 34 and septum 12 shown are chosen for illustration purposes only, to demonstrate the features of the present invention. Other appropriate shapes could be used as well, as long as they impose the radial stresses on the septum that are required for the present invention. The opening and closing of the slit 20 in the septum 12 are accomplished by moving the septum 12 axially within the valve housing 34, with movement of the septum 12 being

accomplished by mating a blunt connector BC to the proximal end 38 of the valve housing 34, as shown in Figure 10. For example, the proximal end 38 of the valve housing 34 could have a female luer fitting formed thereon, as is well known in the art, and the blunt connector BC could be found within a matching male luer connector. The spacing between the wings 42, 44 is designed to allow insertion of the blunt connector BC.

Figure 11 shows the valve element 10 mated with the connector housing 30, with the septum 12 in the proximal position within the valve housing 34. The state shown is the normal disconnected state of the connector. The diameter of the proximal portion of the inside surface 36 of the valve housing 34 is smaller than the major transverse dimension 16 of the septum 12. This applies an inward radial compression to the septum 12 to close the slit 20, as seen in Figure 12, against a pressure differential of at least 30 psi. When the apparatus is in the configuration shown in Figure 12, the wings 42, 44 extend into the slots 29, so that the wings 42, 44 are not imposing a radial stress upon the septum 12. The proximal end surface 15 of the septum 12 preferably has a concave contour 17 shaped to ensure that the inward radial stress applied completely closes the slit, preventing the occurrence of a crevice.

As seen in Figure 13, when the blunt connector BC is mated with the proximal end 38 of the valve housing 34, the septum 12 is pushed distally, partially compressing the spring element 14 and the valve neck 28. This places the septum 12 between the wings 42, 44, which are aligned with the slit plane 22. Since the space between the wings 42, 44 is smaller than the minor transverse dimension 18 of the septum 12, the wings 42, 44 impose inward radial stress on the septum 12 in line with the slit plane 22, causing the slit 20 to open as shown in Figure 14. When the blunt connector BC is disconnected from the valve housing 34, the spring element 14 maintains the proximal end surface 15 of the septum 12 sealed against the blunt connector BC, until the septum 12 has re-entered the constriction at the proximal end of the valve housing 34. This insures that the slit 20 is closed and sealed before the blunt connector BC loses contact with the septum 12, preventing vacuum contamination of the valve assembly 60.

Figures 15 and 16 show a second embodiment of a rigid tubular connector housing 30' with which the valve element 10, 10' can be used. The connector housing 30' includes generally a hollow, substantially cylindrical barrel 32 and a substantially

cylindrical tubular valve housing 34' formed on a proximal end of the barrel 32. The tubular valve housing 34' has an inside surface 36' which interacts with the peripheral surface 13 of the septum 12, 12' to place inward radial stress upon the septum 12, 12' when the septum 12, 12' is in the proximal position, to close the slit 20.

5 The interaction between the inside surface 36' of the valve housing 34' and the peripheral surface 13 of the septum 12, 12' has two modes, one occurring when the septum 12, 12' is positioned near the proximal end 38 of the valve housing 34' and the other occurring when the septum 12, 12' is positioned near the distal end 40 of the valve housing 34'. The proximal portion of the inside surface 36' of the valve housing 34' has
10 a circular cross section. The valve housing 34' is different from the first embodiment, in that it has no wings 42, 44. The internal surface 36' of the distal portion of the valve housing 34' has a conical surface 46' tapering outwardly to a larger diameter 48 at the proximal end 40. Opening of the slit 20 is accomplished by a hollow rigid cannula 62 mounted to the flange 50 by means such as solvent bonding, and extending proximally
15 within the barrel 32. The cannula 62 extends proximally into the distal portion of the valve housing 34'. The proximal end 64 of the cannula 62 aligns with the slit 20 of the septum 12, 12'. As mentioned before, instead of making the septum 12, 12' with an elliptical cross section and the valve housing interior surface 36' with a circular cross section, the septum 12, 12' could be circular and the valve housing 34' could be elliptical.
20 Any such combination of corresponding shapes of the septum 12, 12' and the valve housing 34' which results in an inward radial stress being placed on the septum 12, 12' will comport with the spirit of the invention.

Figures 17 through 21 illustrate the interaction of the valve housing 34' and the septum 12' when assembled as a valve assembly 60'. The particular valve housing 34' and septum 12' shown are chosen for illustration purposes only, to demonstrate the
25 features of the present invention. Other appropriate shapes could be used as well, as long as they impose the radial stresses on the septum that are required for the present invention. The opening and closing of the slit 20 in the septum 12' are accomplished by moving the septum 12' axially within the valve housing 34', with movement of the
30 septum 12' being accomplished by mating a blunt connector BC to the proximal end 38 of the valve housing 34', as shown in Figure 17. For example, the proximal end 38 of the valve housing 34' could have a female luer fitting formed thereon, as is well known in the

art, and the blunt connector BC could be found within a matching male luer connector. The internal diameter of the surface 36' is designed to allow insertion of the blunt connector BC.

Figure 18 shows the valve element 10' mated with the connector housing 30', with the septum 12' in the proximal position within the valve housing 34'. Valve element 10 could also be used. The state shown is the normal disconnected state of the connector. The diameter of the proximal portion of the inside surface 36' of the valve housing 34' is smaller than the major transverse dimension 16 of the septum 12'. This applies an inward radial compression to the septum 12' to close the slit 20, as seen in Figure 19. The proximal end surface 15 of the septum 12' preferably has a concave contour shaped to insure that the inward radial stress applied completely closes the slit, preventing the occurrence of a crevice.

As seen in Figure 20, when the blunt connector BC is mated with the proximal end 38 of the valve housing 34', the septum 12' is pushed distally, partially compressing the spring element 14 and the valve neck 28. This causes the septum 12' to contact the proximal end 64 of the hollow cannula 62. As the hollow cannula 62 enters the slit 20, it imposes outward radial stress on the septum 12', causing the slit 20 to open as shown in Figure 21. It is important to note that internal contours of the valve housing 34' and the axial position of the proximal end 64 of the cannula are designed so that the proximal end 64 of the cannula 62 does not extend far enough in the proximal direction to contact the blunt cannula BC when the blunt cannula BC has been inserted completely into the connector housing 30'. This is because, even though the length, taper angle, and outside diameter of the blunt connector BC are controlled by industry standards, the internal diameter of the blunt connector BC is not a controlled dimension.

When the blunt connector BC is disconnected from the valve housing 34', the spring element 14 maintains the proximal end surface 15 of the septum 12' sealed against the blunt connector BC, until the septum 12' has re-entered the constriction at the proximal end of the valve housing 34'. This insures that the slit 20 is closed and sealed before the blunt connector BC loses contact with the septum 12', preventing vacuum contamination of the valve assembly 60'.

Figure 22 shows a third embodiment of the valve element 10'' according to the present invention. This embodiment is a hollow, combination elastomeric valve element

10'' comprising a septum 12'' and a spring element 14. In this view, the valve element 10'' is in the unconstrained condition. The spring element can be a resilient elastomeric cylinder as shown, or it can be a spring, such as a coiled spring, in substantially the same location. If a coiled spring is used, it can be separate from the valve element 10'' or
5 integrated into the valve element 10''. The septum 12'' shown has an elliptical cross section, with a major transverse dimension, or major axis 16, and a minor transverse dimension, or minor axis 18. This particular embodiment of the septum has a fairly high aspect ratio. The septum 12'' has a peripheral surface 13'' and a proximal end surface 15. The septum 12'' also could be another non-cylindrical shape without departing from the
10 spirit of the invention. Further, depending upon the shape of other elements of the valve, the septum 12'' could even have a cylindrical shape. A slit 20 is formed longitudinally through the septum 12''. The cross section of the slit 20 can be a flat line, or slightly oval as shown, with a slit plane 22. The slit plane 22 in this embodiment is aligned with the major transverse dimension 16 of the septum 12''. The end surface 15 has a concave
15 surface 17 which ensures that the outer end of the slit 20 remains closed.

Figure 23 shows a longitudinal cross section of the valve element 10'', with the section being taken at the slit plane 22. The longitudinal axis 24 of the valve element 10'' can lie in the slit plane 22, or it can be offset therefrom. The valve element 10'' also can have a sealing bead 26 near its distal end, to facilitate sealing the valve element to a
20 housing, such as a Y-site. The configuration and location of the sealing member 26 can vary, to match the housing in which the valve element 10'' is used. There can also be a tapered neck 28 in the valve element 10'', to allow relative axial movement between the septum 12'' and the remainder of the valve element 10''. The neck 28 is also an alternative location for a spring element. Figure 24 shows another longitudinal cross
25 section of the valve element 10'', with the section being taken orthogonal to the slit plane 22. It can be seen from Figures 22 through 24 that the aspect ratio between the major transverse dimension 16 and the minor transverse dimension 18 of the septum 12'' is fairly high, so the septum 12'' is far from being cylindrical in this embodiment.

Figure 25 shows a third embodiment of a rigid tubular connector housing 30''
30 with which the valve element 10'' can be used. The connector housing 30'' includes generally a hollow, substantially cylindrical barrel 32 and a substantially cylindrical tubular valve housing 34'' formed on a proximal end of the barrel 32. The connector

housing 30'' can also be fitted with a flange 50 for sealing against the sealing bead 26 of the valve element 10'', if appropriate for the type of connector. The configurations shown for the distal ends of the connector housing 30'' and the valve element 10'', such as the flange 50 and the sealing element 26, are for illustration purposes only, with the actual configuration being adapted to the actual connector being designed. The tubular valve housing 34'' has an inside surface 36'' which interacts with the peripheral surface 13'' of the septum 12'', to place inward radial stress upon the septum 12'' as desired to close the slit 20.

The interaction between the inside surface 36'' of the valve housing 34'' and the peripheral surface 13'' of the septum 12'' has two modes, one occurring when the septum 12'' is positioned near the proximal end 38 of the valve housing 34'' and the other occurring when the septum 12'' is positioned near the distal end 40 of the valve housing 34''. In this embodiment, the proximal portion of the inside surface 36'' of the valve housing 34'' has a circular cross section, as can be seen in Figures 26 and 27. The distal portion of the inside surface 36'' of the valve housing 34'' has a conical surface 46 tapering outwardly to an elliptical surface 48' at the distal end 40, as shown in Figure 26 and 27. As mentioned above, instead of making the septum 12'' with an elliptical cross section and the proximal portion of the valve housing interior surface 36'' with a circular cross section, the septum 12'' could be circular and the proximal portion of the valve housing 34'' could be elliptical. In the latter case, the distal portion of the inside surface 36'' of the valve housing 34'' would have a conical surface 46 tapering outwardly to a cylindrical surface 48' at the distal end 40. Any such combination of corresponding shapes of the septum 12'' and the valve housing 34'' which results in an inward radial stress being placed on the septum 12'' by the proximal portion of the interior surface 36'' will comport with the spirit of the invention.

Figures 28 through 31 illustrate the interaction of the valve housing 34'' and the septum 12'', when assembled as a valve assembly 60''. The particular valve housing 34'' and septum 12'' shown are chosen for illustration purposes only, to demonstrate the features of the present invention. Other appropriate shapes could be used as well, as long as they vary the radial stresses on the septum that are required for the present invention. The opening and closing of the slit 20 in the septum 12'' are accomplished by moving the septum 12'' axially within the valve housing 34'', with movement of the septum 12''

being accomplished by mating a blunt connector BC to the proximal end 38 of the valve housing 34'', as shown above relative to the other embodiments. For example, the proximal end 38 of the valve housing 34'' could have a female luer fitting formed thereon, as is well known in the art, and the blunt connector BC could be found within a matching male luer connector.

Figure 28 shows the valve element 10'' mated with the connector housing 30'', with the septum 12'' in the proximal position within the valve housing 34''. The state shown is the normal disconnected state of the connector. The diameter of the proximal portion of the inside surface 36'' of the valve housing 34'' is smaller than the minor transverse dimension 18 of the septum 12''. This applies an inward radial compression to the septum 12'' to close the slit 20, as seen in Figure 29, against a pressure differential of at least 30 psi. The proximal end surface 15 of the septum 12 preferably has a concave contour 17 shaped to ensure that the inward radial stress applied completely closes the slit, preventing the occurrence of a crevice.

As seen in Figure 30, when the blunt connector BC is mated with the proximal end 38 of the valve housing 34'', the septum 12'' is pushed distally, partially compressing the spring element 14 and the valve neck 28. This places the septum 12'' in the elliptical cavity described by the elliptical surface 48'. Since the major and minor transverse dimensions of this elliptical cavity are larger than the major and minor transverse dimensions 16, 18 of the septum 12'', the elliptical surface 48' does not impose any inward radial stress on the septum 12'' in line with the slit plane 22. This allows the septum 12'' to expand, causing the slit 20 to open as shown in Figure 31. When the blunt connector BC is disconnected from the valve housing 34'', the spring element 14 maintains the proximal end surface 15 of the septum 12'' sealed against the blunt connector BC, until the septum 12'' has re-entered the constriction at the proximal end of the valve housing 34''. This insures that the slit 20 is closed and sealed before the blunt connector BC loses contact with the septum 12'', preventing vacuum contamination of the valve assembly 60''.

While the particular invention as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages hereinbefore stated, it is to be understood that this disclosure is merely illustrative of the presently preferred embodiments of the invention and that no limitations are intended other than as described in the appended claims.

CLAIMS

We claim:

1. A valve assembly for connecting intravascular fluid flow components, said valve assembly comprising:

a substantially tubular housing;

a compressible elastomeric septum slidably disposed within said tubular housing for axial movement between a proximal position and a distal position of said septum;

a biasing element configured and positioned to bias said septum toward said proximal position;

a slit formed axially through said septum;

a first interior contour within said tubular housing, said first contour being smaller than a transverse dimension of said septum, for compressing said transverse dimension when said septum is in said proximal position, thereby holding said slit in a closed state; and

a second interior contour within said tubular housing, said second contour being located distally from said first contour, said second interior contour being shaped and sized to effect the opening of said slit when said septum is in said distal position;

wherein said septum is slidable from said proximal position to said distal position by application of an axial force to a proximal surface of said septum.

2. A valve assembly as claimed in claim 1, wherein said first interior contour is formed on an inner wall of said tubular housing, said first interior contour having a transverse dimension less than said first transverse dimension of said septum, said first transverse dimension of said septum being orthogonal to said slit, said transverse dimension of said first interior contour aligning with said first transverse dimension of said septum when said septum is in said proximal position, thereby compressing said first transverse dimension of said septum from a first value to a smaller second value, to close said slit.

1 3. A valve assembly as claimed in claim 2, wherein said first interior contour
2 on said inner wall of said tubular housing comprises a substantially circular contour, said
3 circular contour creating a circular lumen having a diameter less than said first transverse
4 dimension of said septum.

1 4. A valve assembly as claimed in claim 2, wherein said first interior contour
2 on said inner wall of said tubular housing comprises an inwardly projecting contour, said
3 inwardly projecting contour creating a non-circular lumen having a transverse dimension
4 less than said first transverse dimension of said septum.

1 5. A valve assembly as claimed in claim 2, wherein said septum has a circular
2 cross section at said first transverse dimension.

1 6. A valve assembly as claimed in claim 2, wherein said septum has a non-
2 circular cross section at said first transverse dimension.

1 7. A valve assembly as claimed in claim 1, wherein said second interior
2 contour within said tubular housing is shaped and sized to apply substantially radial force
3 to a second transverse dimension of said septum when said septum is in said distal
4 position, to hold said slit in said open state.

1 8. A valve assembly as claimed in claim 7, wherein said second interior
2 contour comprises a second contour on an inner wall of said tubular housing, said second
3 interior contour having a transverse dimension less than said second transverse dimension
4 of said septum, said second transverse dimension of said septum being parallel to said slit,
5 said transverse dimension of said second interior contour aligning with said second
6 transverse dimension of said septum when said septum is in said distal position, thereby
7 applying an inward radial force compressing said second transverse dimension of said
8 septum from a first value to a smaller second value, to open said slit.

1 9. A valve assembly as claimed in claim 8, wherein said second interior
2 contour on said inner wall of said tubular housing comprises a substantially circular
3 contour, said circular contour creating a circular lumen having a diameter less than said
4 second transverse dimension of said septum.

1 10. A valve assembly as claimed in claim 8, wherein said second interior
2 contour on said inner wall of said tubular housing comprises an inwardly projecting
3 contour, said inwardly projecting contour creating a non-circular lumen having a
4 transverse dimension less than said second transverse dimension of said septum.

1 11. A valve assembly as claimed in claim 8, wherein said septum has a circular
2 cross section at said second transverse dimension.

1 12. A valve assembly as claimed in claim 8, wherein said septum has a non-
2 circular cross section at said second transverse dimension.

1 13. A valve assembly as claimed in claim 7, wherein:
2 said second interior contour comprises a cannula formed within a distal portion of
3 said tubular housing;
4 said cannula has a proximal end substantially aligned with said slit to cause said
5 cannula to enter said slit when said septum moves to said distal position,
6 thereby applying an outward radial force to said septum, to open said slit;
7 and
8 said proximal end of said cannula extends only partially through said slit when
9 said septum is in said distal position.

1 14. A valve assembly as claimed in claim 1, wherein said second interior
2 contour within said tubular housing is at least as large as said transverse dimension of said
3 septum, for eliminating compression of said transverse dimension when said septum is in
4 said distal position, thereby allowing said slit to assume an open state.

1 15. A valve assembly as claimed in claim 14, wherein each transverse
2 dimension of said second interior contour in said housing is greater than each
3 corresponding transverse dimension of said septum, when said septum is in said distal
4 position, thereby eliminating application of any radial force to said septum, to allow said
5 slit to open solely as a result of transverse expansion of said septum.

1 16. A valve assembly as claimed in claim 15, wherein said second interior
2 contour in said tubular housing comprises a substantially circular contour, said circular
3 contour creating a circular lumen having a diameter greater than any said transverse
4 dimension of said septum.

1 17. A valve assembly as claimed in claim 16, wherein said septum has a
2 circular cross section at said transverse dimension.

1 18. A valve assembly as claimed in claim 15, wherein said second interior
2 contour in said tubular housing comprises a non-circular lumen.

1 19. A valve assembly as claimed in claim 18, wherein said septum has a non-
2 circular cross section at said transverse dimension.

1 20. A valve assembly as claimed in claim 1, further comprising a substantially
2 concave contour formed on a proximal surface of said septum, wherein said concave
3 contour on said septum and said first interior contour within said housing are constructed
4 and axially located so as to close said slit at a proximal end of said slit, and to seal said
5 slit against a selected pressure differential at an intermediate depth within said slit.

1 21. A valve assembly as claimed in claim 20, wherein said first interior
2 contour seals said slit against a pressure differential of at least 30 psi.

1 22. A valve assembly as claimed in claim 1, wherein said first interior contour
2 in said tubular housing and said transverse dimension of said septum are formed at
3 relative axial positions which result in said application of said compressive force to said
4 septum through a finite range of axial movement of said septum, thereby closing said slit
5 as said septum moves from said distal position toward said proximal position while said
6 biasing element still maintains a sealing engagement between a proximal surface of said
7 septum and a fitting being disconnected from said proximal portion of said tubular
8 housing, and thereby maintaining said slit in a closed state as said septum moves from
9 said proximal position toward said distal position until said biasing element achieves a
10 sealing engagement between said proximal surface of said septum and a fitting being
11 connected to said proximal portion of said tubular housing.

1/10



FIG. 1

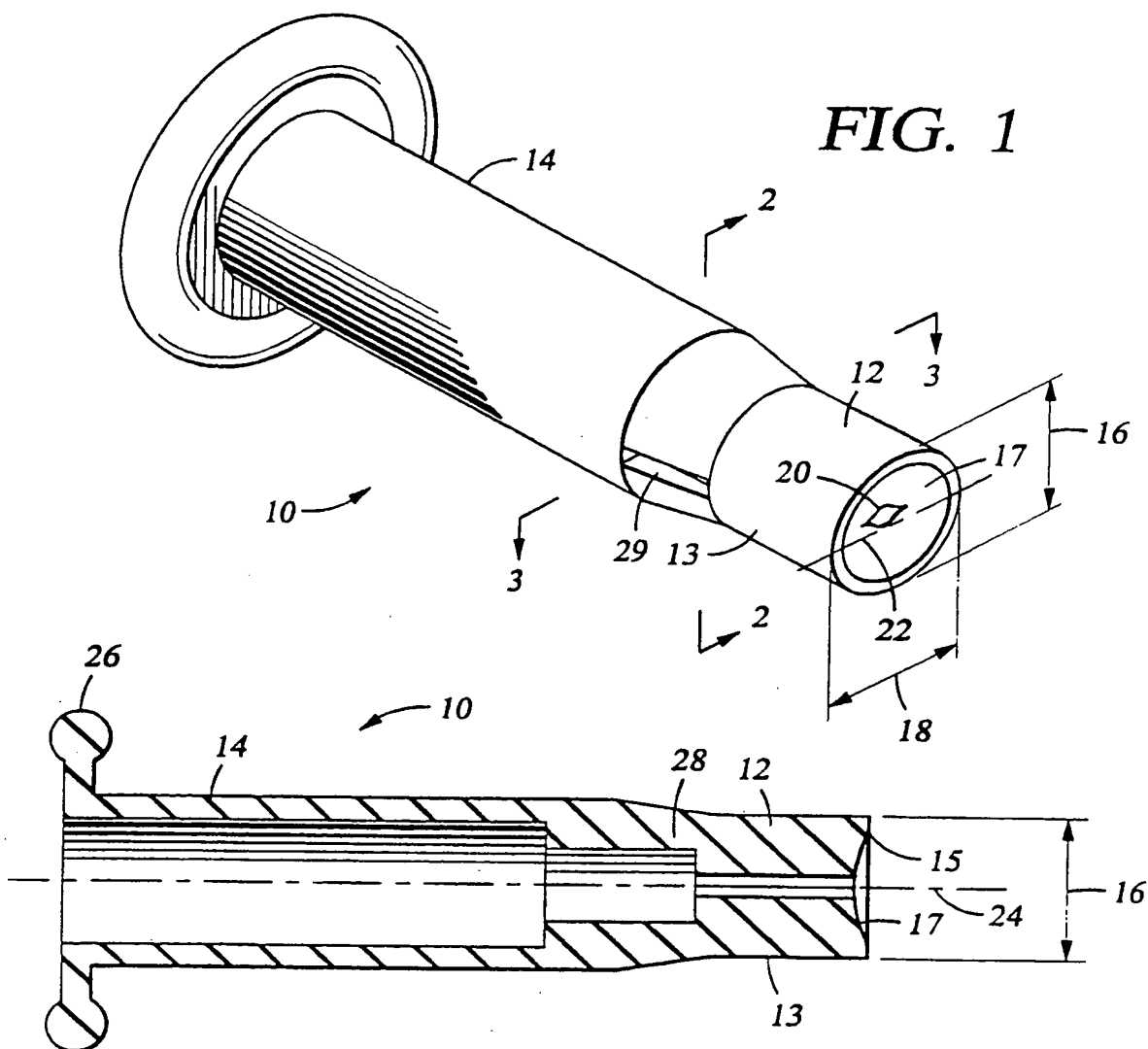


FIG. 2

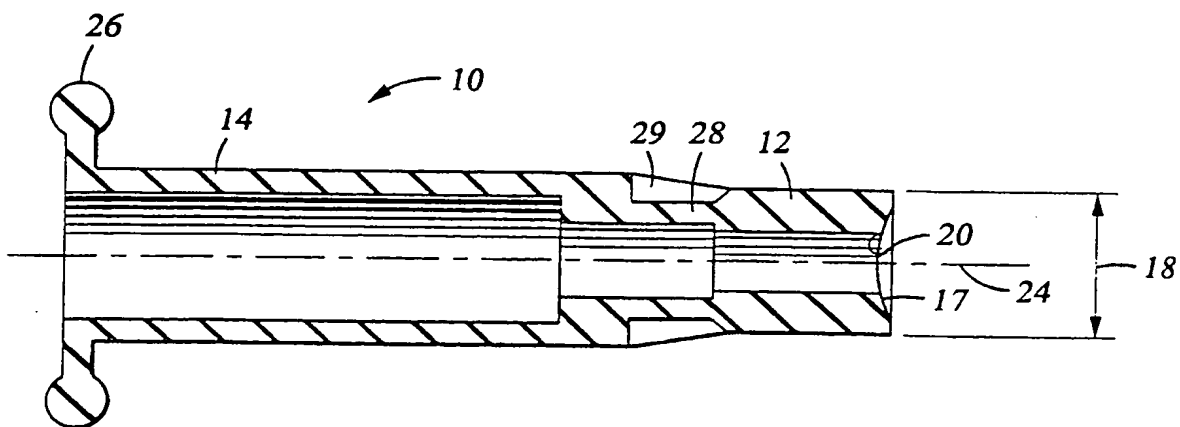


FIG. 3

SUBSTITUTE SHEET (RULE 26)



2/10

FIG. 4

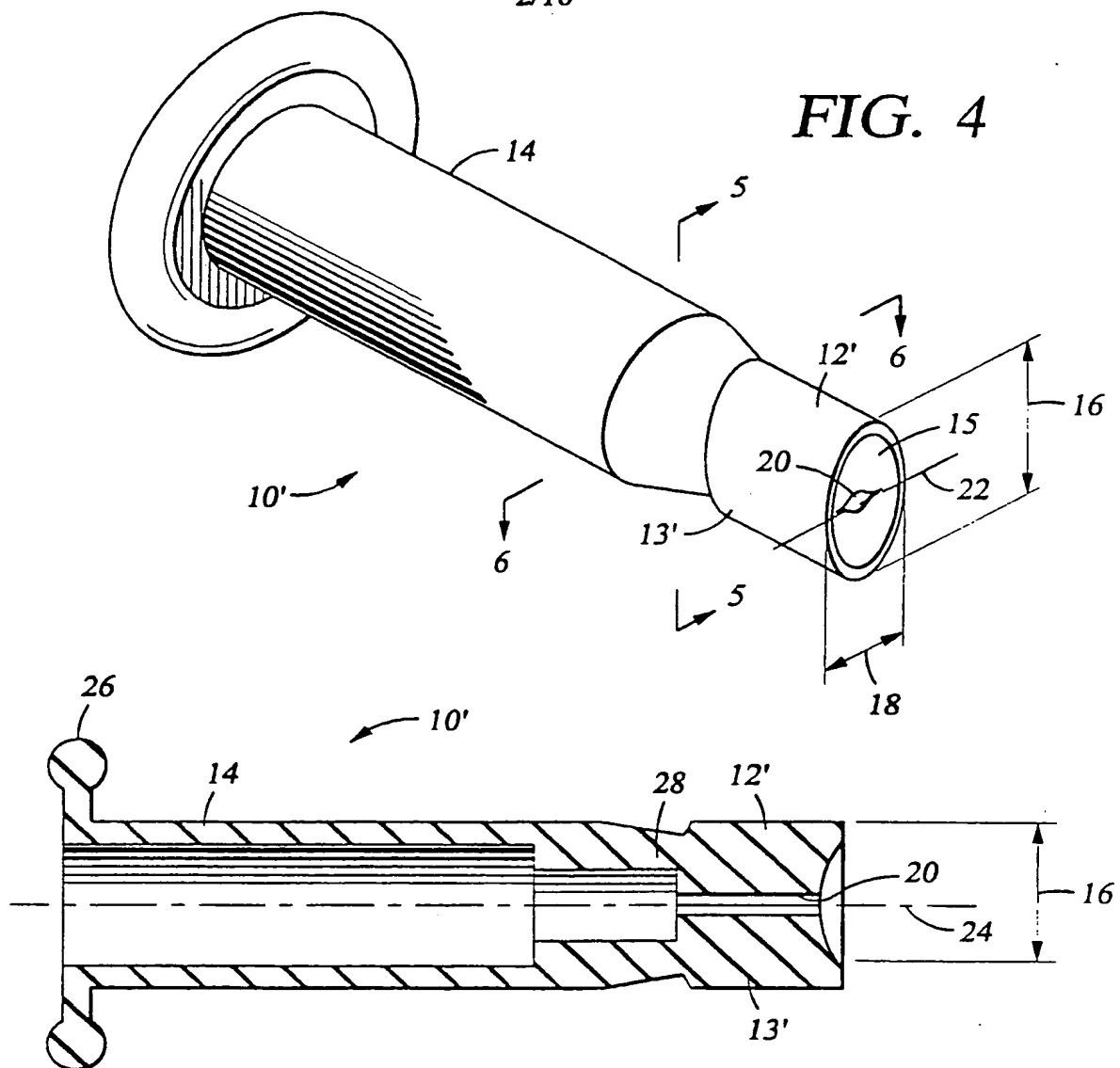


FIG. 5

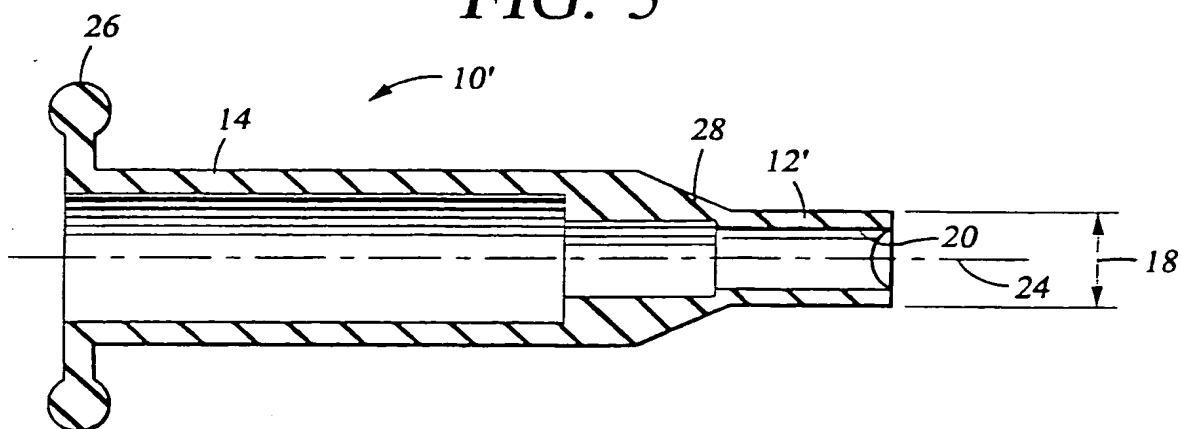
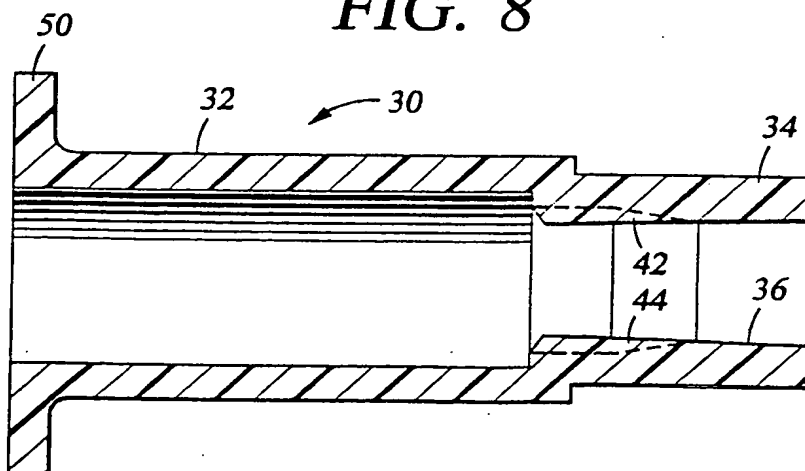
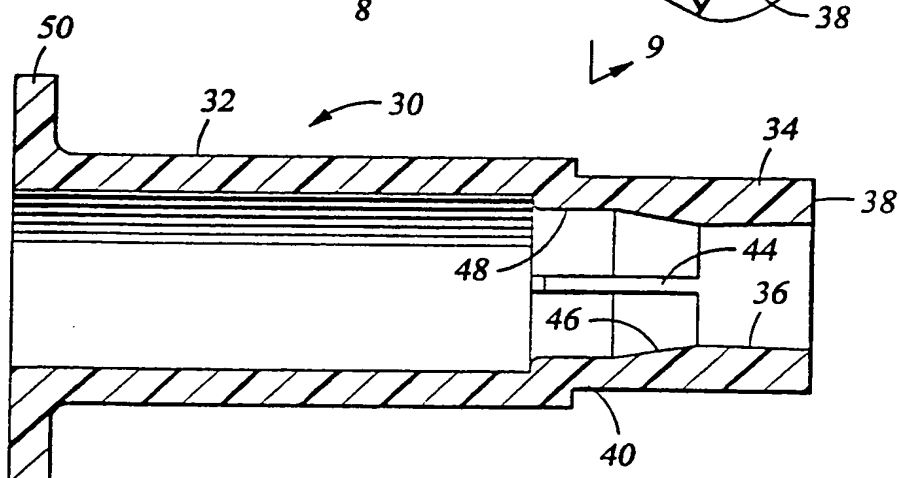
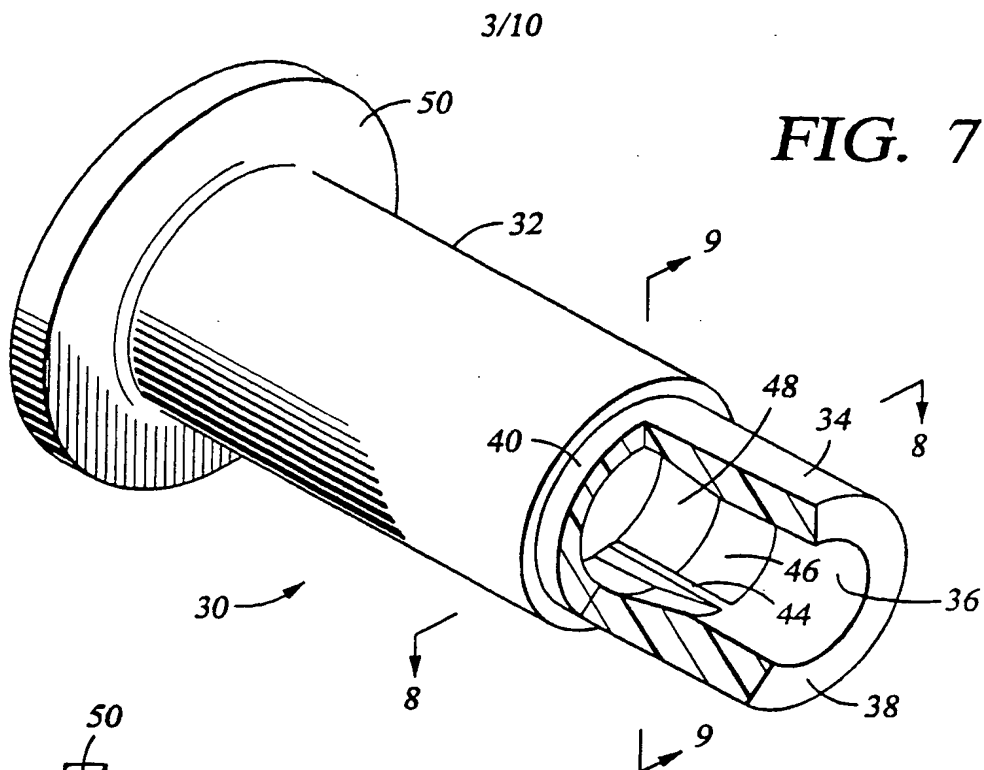


FIG. 6





4/10

FIG. 10

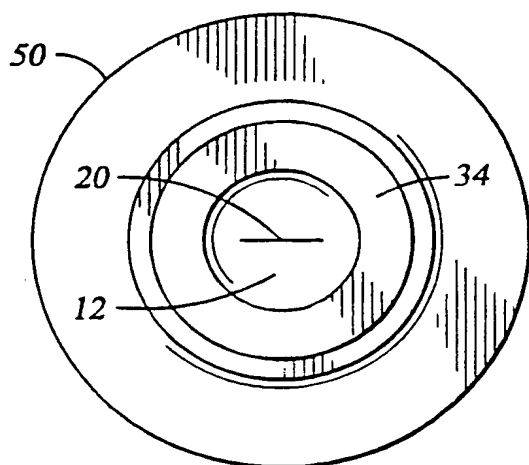
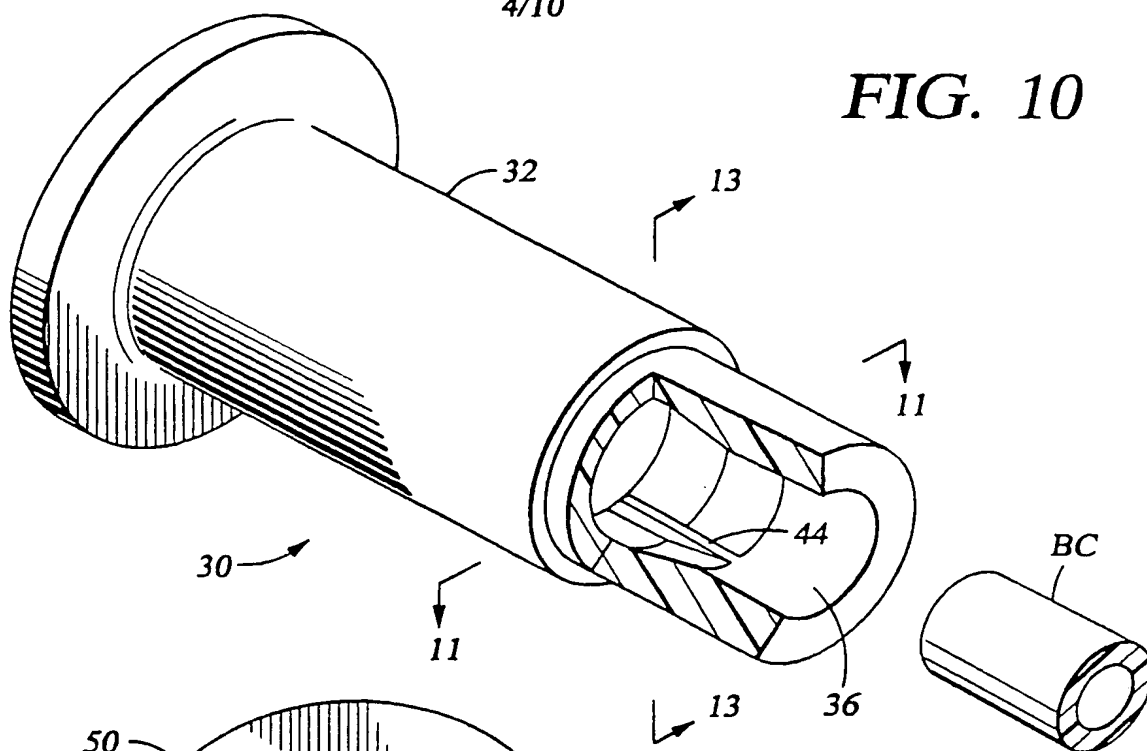


FIG. 12

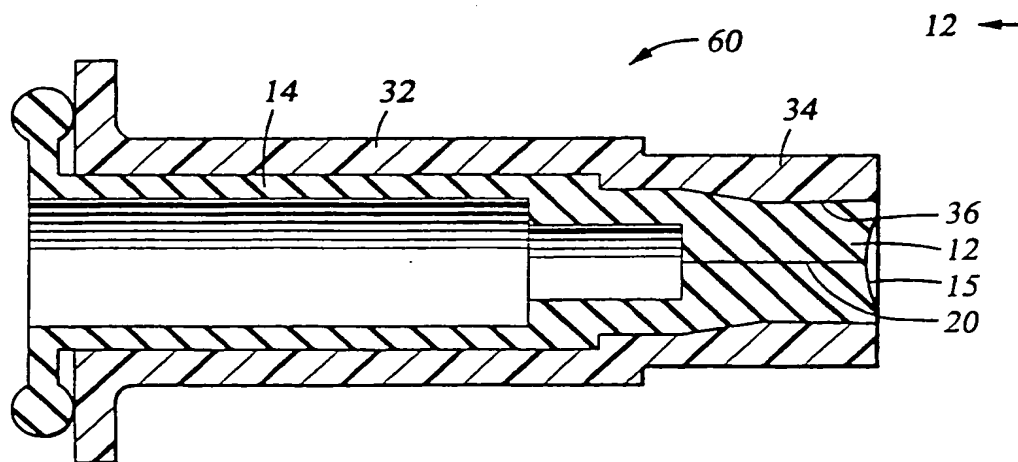


FIG. 11

5/10

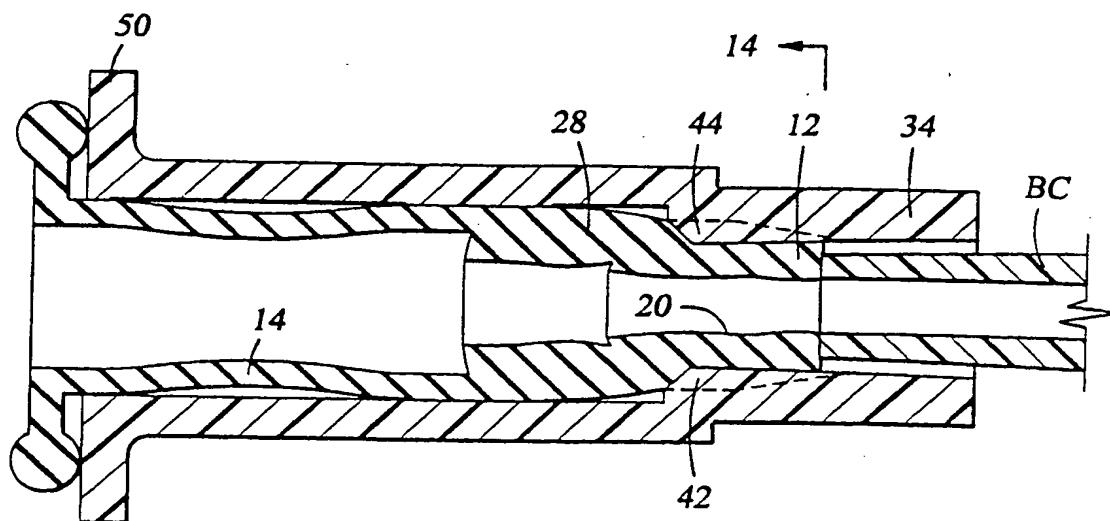


FIG. 13

FIG. 14

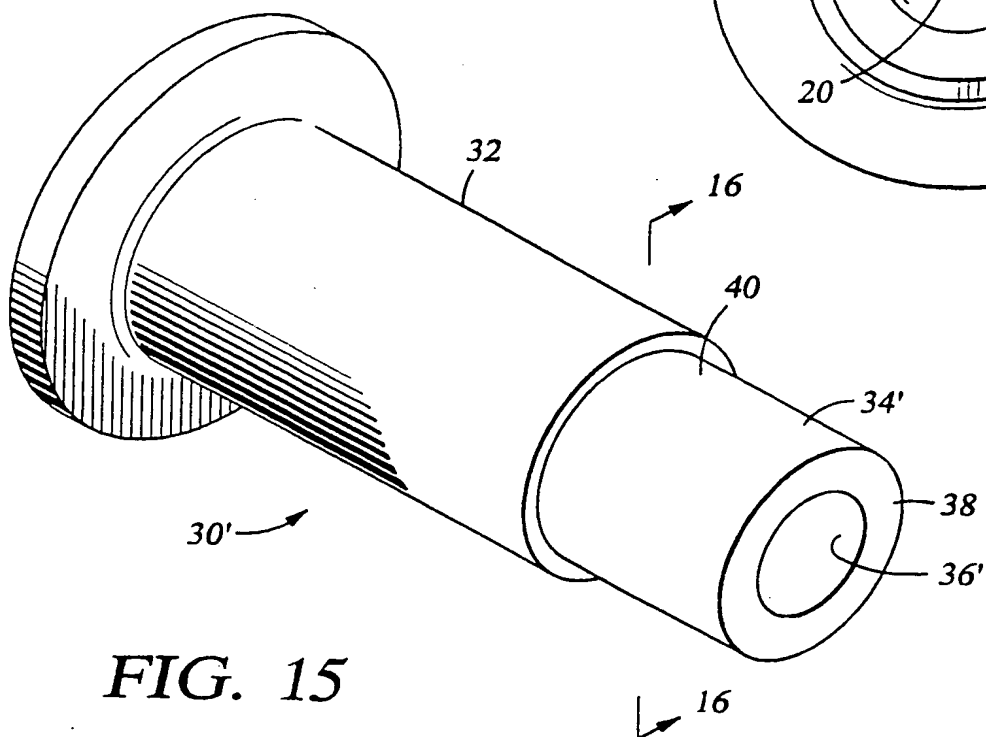
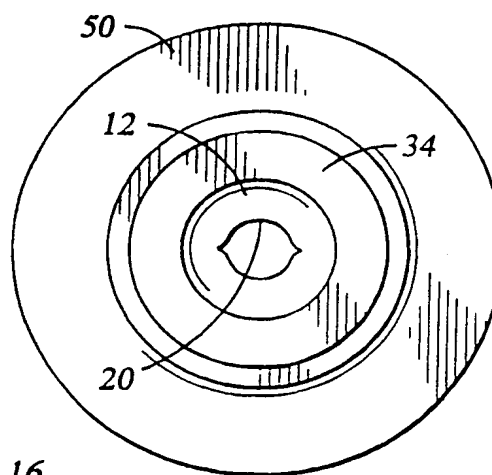


FIG. 15

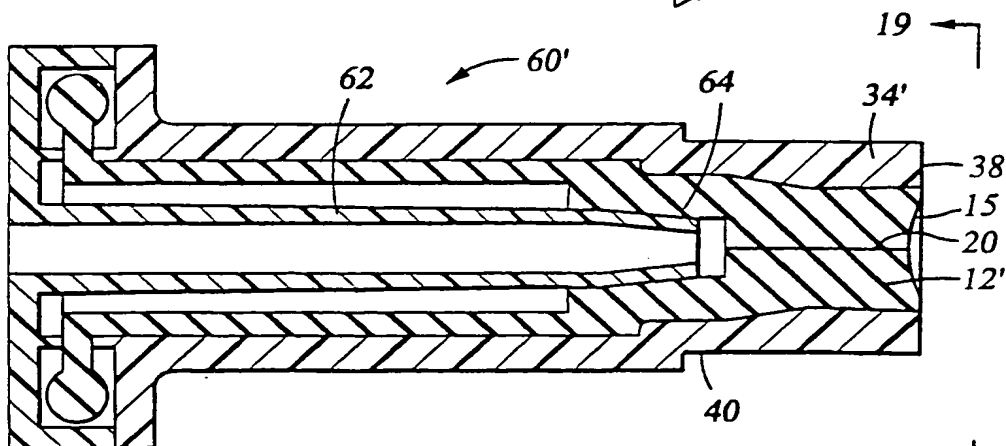
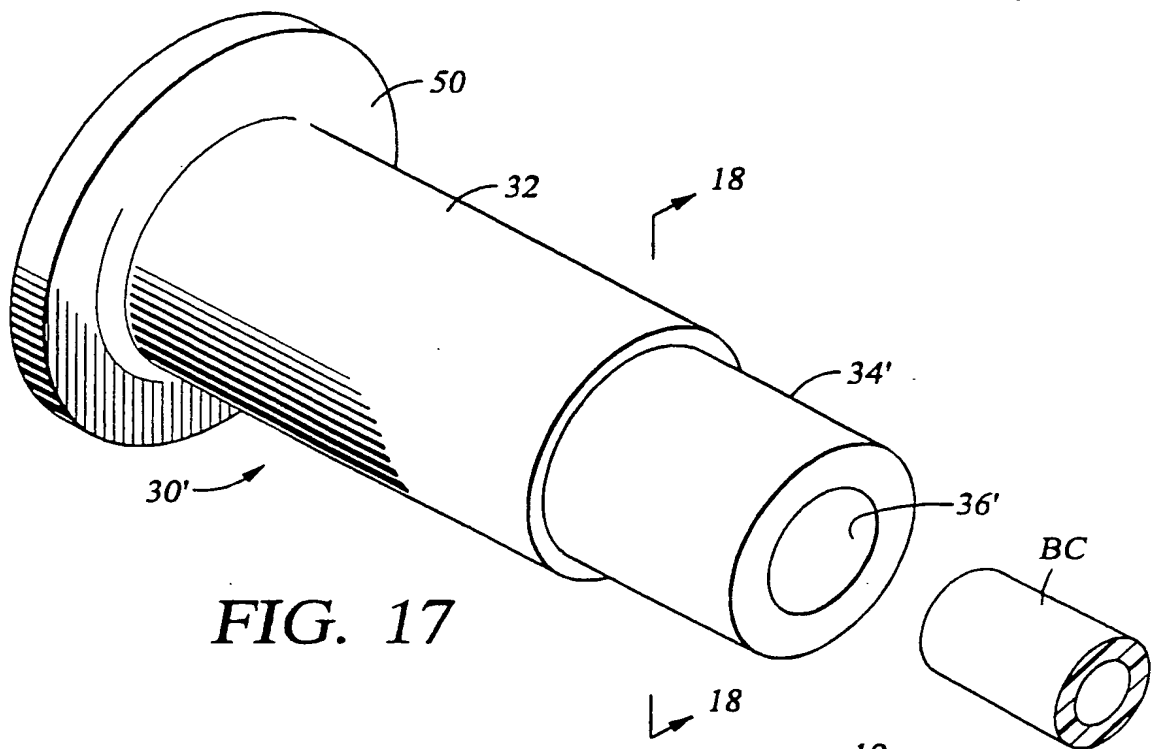
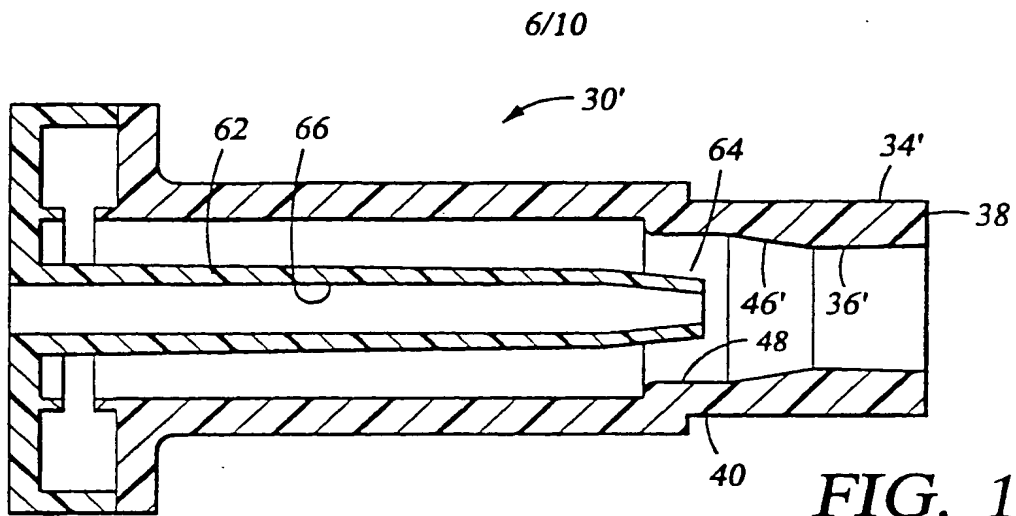


FIG. 18

SUBSTITUTE SHEET (RULE 26)

7/10



FIG. 19

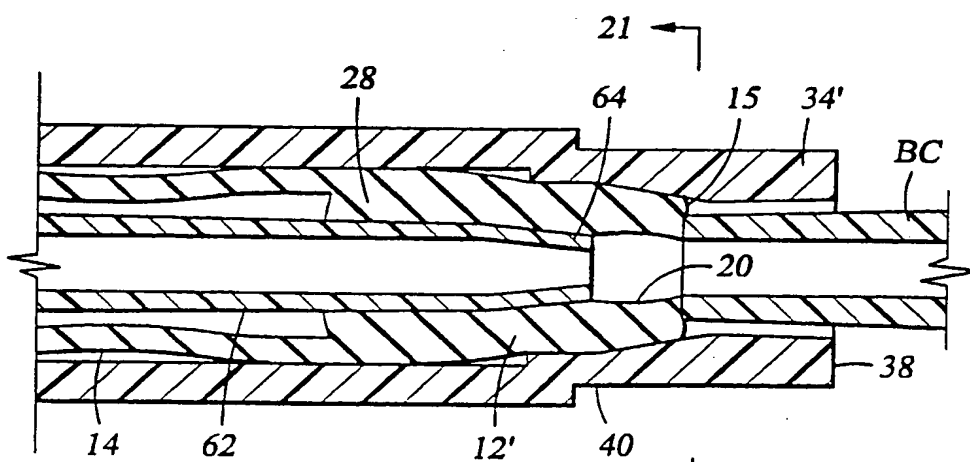
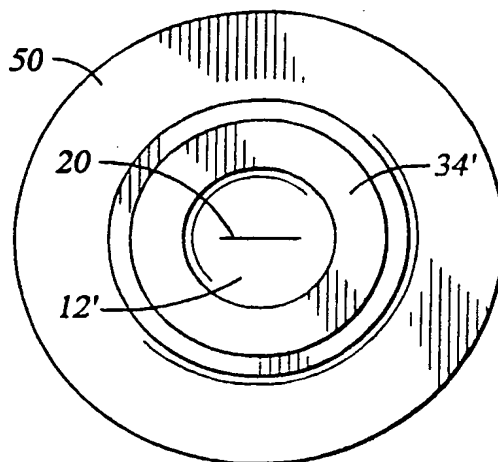
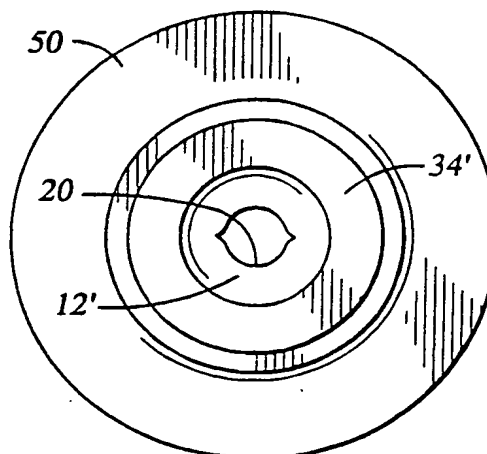


FIG. 20

FIG. 21



8/10



FIG. 22

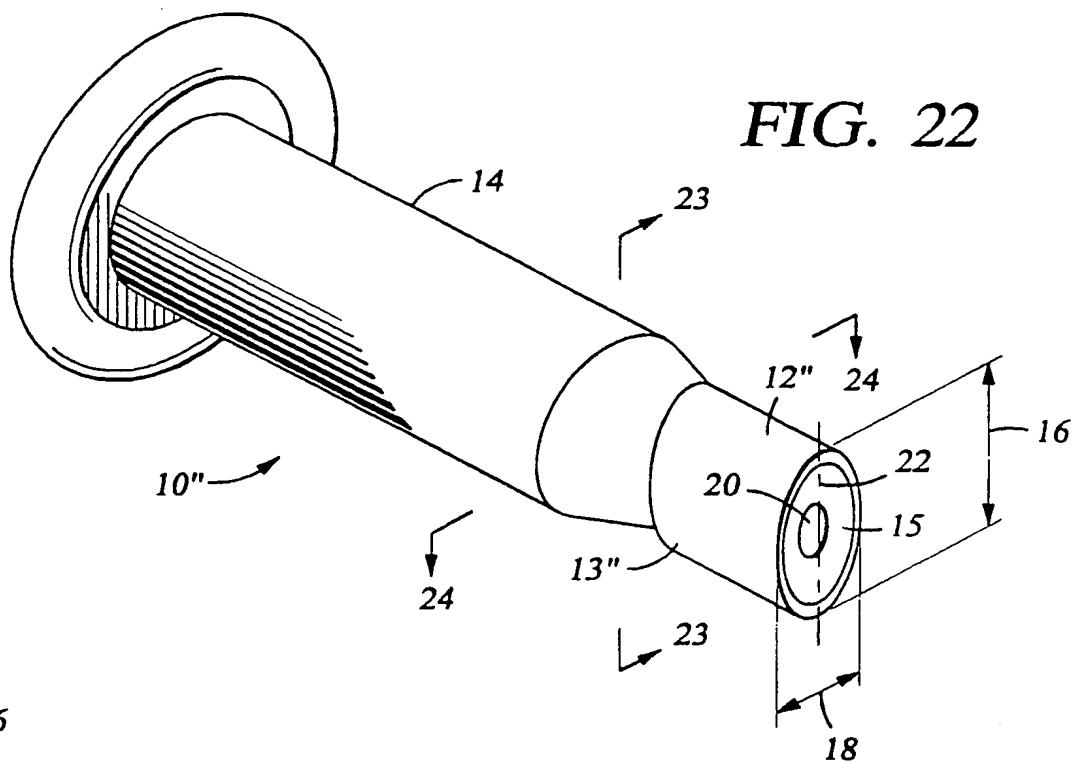


FIG. 23

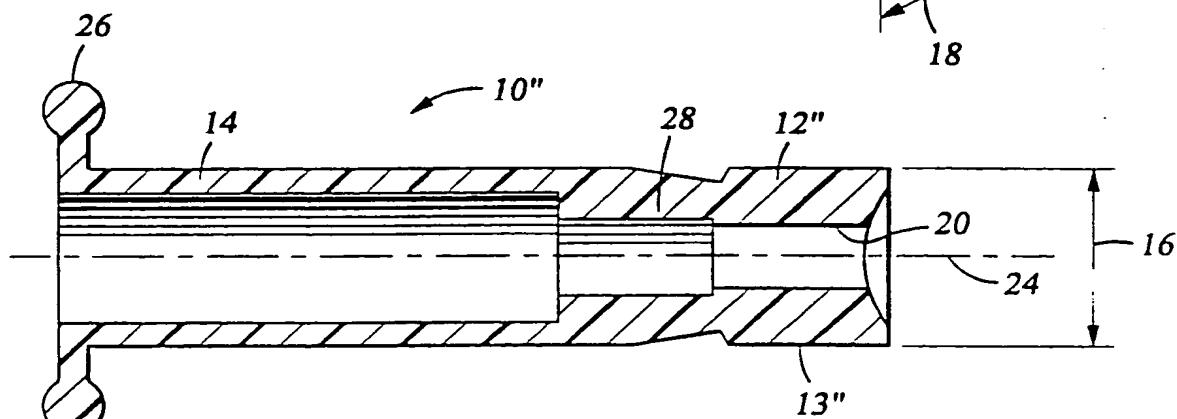
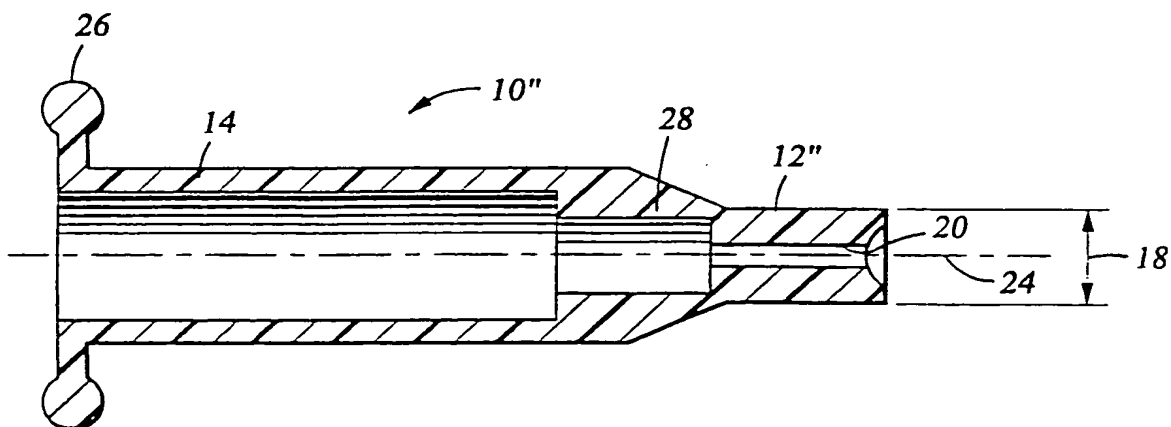


FIG. 24



9/10

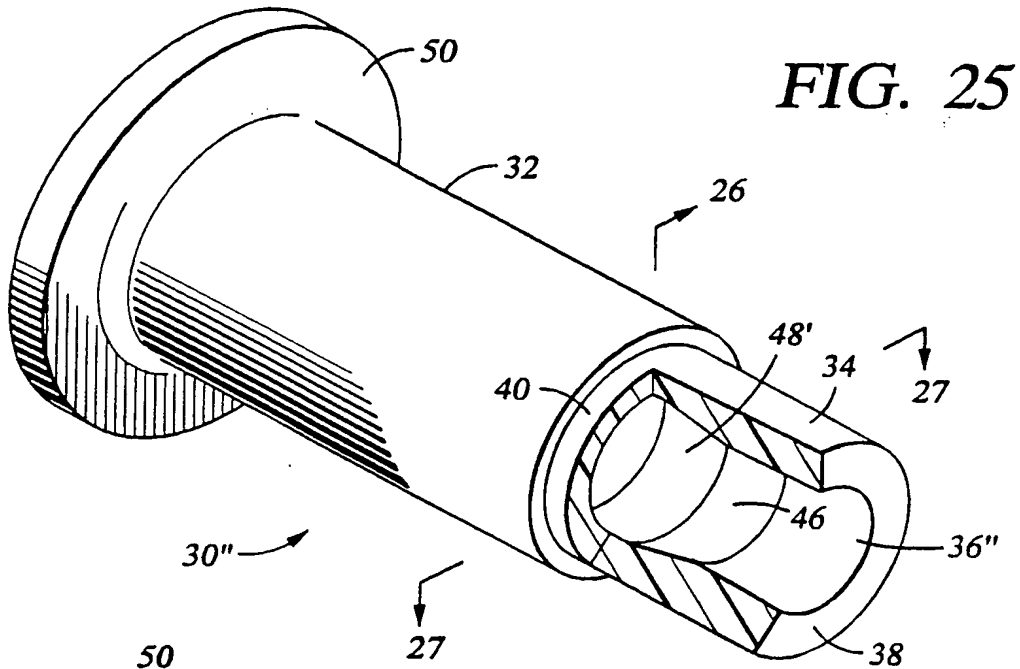


FIG. 25

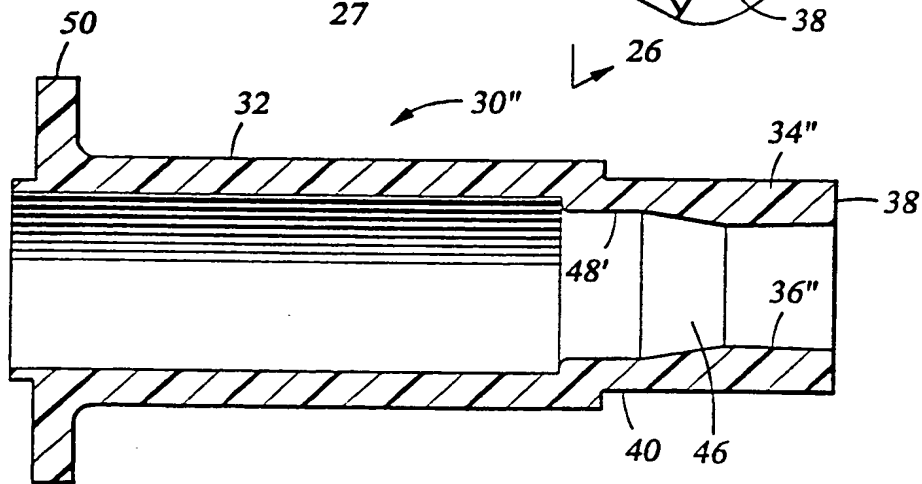


FIG. 26

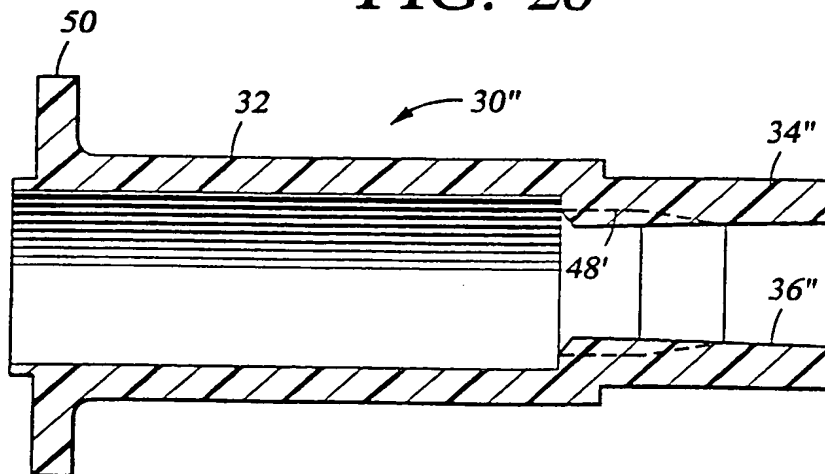


FIG. 27

SUBSTITUTE SHEET (RULE 26)

10/10

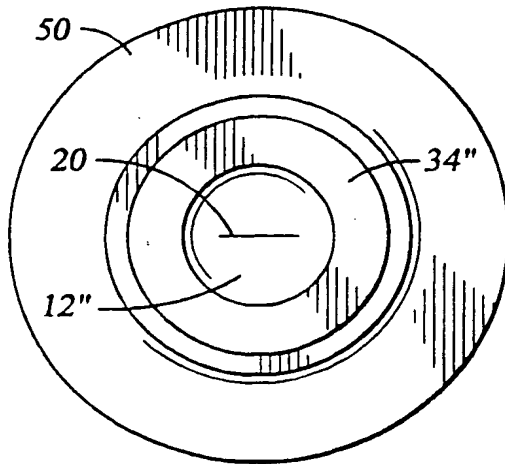


FIG. 29

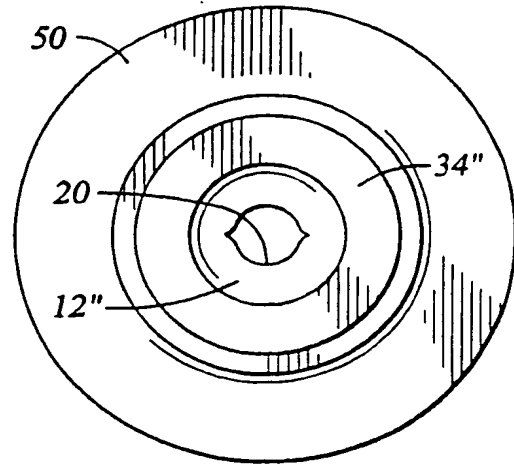


FIG. 31

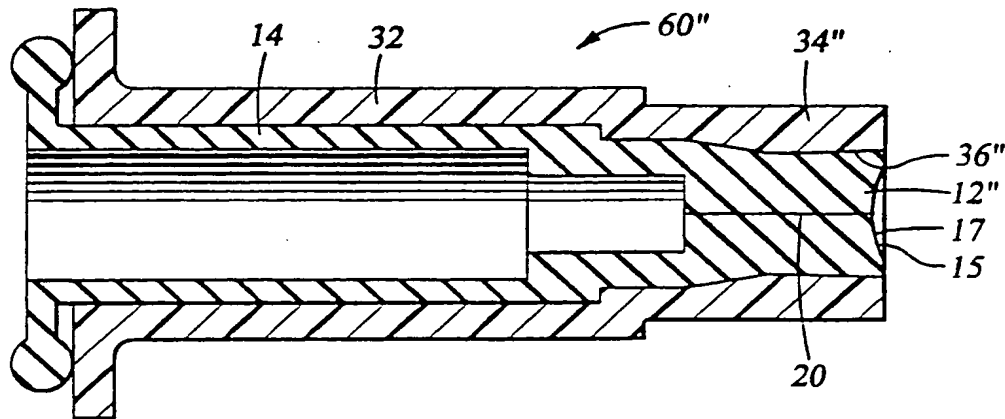


FIG. 28

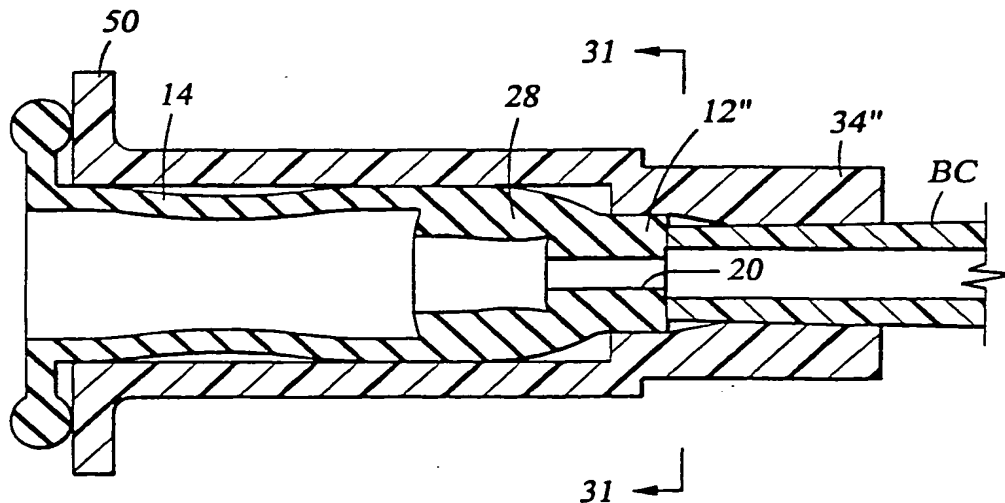


FIG. 30

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21521

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/00

US CL :604/246

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 251/159.1; 604/82, 83, 86, 88, 89, 167, 169, 247, 256, 280, 283

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,203,775 A (FRANK et al) 20 April 1993, entire document.	1-22
A	US 5,242,393 A (BRIMHALL et al) 07 September 1993, entire document.	1-22
A	US 5,251,873 A (ATKINSON et al) 12 October 1993, entire document.	1-22



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

22 JANUARY 1998

Date of mailing of the international search report

17 FEB 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JOHN YASKO, JR.

Telephone No. (703) 308-2986